**NHS TAYSIDE RISK ASSESSMENT FORM**

**Advanced Therapy Medicinal Product (not a GMO) Part 1**

This form applies only to clinical research studies involving Advanced Therapy Investigational Medicinal Products (ATIMPs) that are not Genetically Modified Organisms (GMOs). It is recommended that the Principal Investigator discuss their clinical research study with the Biological Safety Officer or Secretary of the NHS Tayside Advanced Therapy and Gene Modification Safety Committee (ATGMSC) and refer to the TASC ATGMSC Standard Operating Procedure (SOP) before completing and submitting this form.

|  |  |
| --- | --- |
| **FOR COMMITTEE USE ONLY** |  |
| Risk Assessment Version Number |  |
| Date Received by ATGMSC Secretary |  |
| ATGMSC Reference | AT |

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**Section 1: Details of Proposed Research Study**

**1.1 – Study Details**

|  |  |
| --- | --- |
| IRAS number |  |
| Study full title |  |
| Study short title |  |
| Planned start date for recruitment |  |
| Planned end of study date |  |
| Location - Ninewells Hospital | *Please identify all rooms/facilities where ATIMPs will be handled and stored.* |

**1.2 – Principal Investigator (PI) Details**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator |  | Position |  |
| Department |  | | |
| Full postal address |  | | |
| E-mail address |  | Phone no |  |

**1.3 – Alternative Contact Details**

Person who will have responsibility in the absence of the PI.

|  |  |  |  |
| --- | --- | --- | --- |
| Alternative contact |  | Position |  |
| Full postal address |  | | |
| E-mail address |  | Phone no |  |

**Section 2: Approvals, Consents, Notifications and Licences**

Give details of approvals/notifications for this research study.

|  |  |  |
| --- | --- | --- |
|  | **Reference Number** | **Date approved or notification date if not yet approved** |
| Research Ethics Committee (REC)/Gene Therapy Advisory Committee (GTAC) |  |  |
| Medicines & Healthcare products Regulatory Agency (MHRA) |  |  |
| Status of any notification to Health & Safety Executive (HSE) if applicable |  |  |
| GMO release consent for research and development (Scotland) if applicable <https://www.gov.uk/gmo-release-consent-research-development-scotland> |  |  |

**Section 3: Lay Summary of the Research Study**

A summary of the research study, its background, goals and the justification of the research should be detailed in a manner that may be understood by all reviewers. This should include the patient pathway and not exceed 400 words.

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| --- |
| *Can refer to Lay Summary from Integrated Research Application System* (*IRAS) Form.* |

**Section 4: Scientific Detail of the Research**

Detail of the proposed research including the scope of the research.

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| --- |
| *Write in free text, no more than 3 paragraphs.* |

**Section 5:** **Arrangements to Control Risk**

Consider the list of issues in the table below and detail how the risks posed by the ATIMP will be controlled for each item. Reference should be made to Standard Operating Procedures (SOPs). These may be existing TASC, local or Study Specific SOPs.

| **5.1 - Administration to Patient** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| Will safeguards against aerosols be required during patient administration? How will this be achieved? |  |
| How long will the patient have to remain in hospital following administration of the Advanced Therapy Investigational Medicinal Product (ATIMP)? Where will they be transferred to (if applicable)? |  |
| Are there risks to personnel other than patients?  Will visitors be permitted? |  |

| **5.2 - Patient Care** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| Will clinical samples (e.g. fluids, tissues) be collected from the patient for routine analysis by hospital laboratories? Specify arrangements for their safe handling. |  |
| Specify clinical samples to be collected for specialised analysis by research laboratories? Specify arrangements for their safe handling. |  |
| Identify any specific precautions or restrictions required for visitors to the patient. |  |
| Will the patient need to be transported within the hospital following administration of the ATIMP? Identify any specific safety procedures required for such transportation of the patient. |  |
| Identify any actions to be taken should the patient suffers from an iatrogenic infection.  Will the patient require transport to another location? |  |
| Identify any specific safety arrangements required if it is necessary to evacuate the patient in the event of fire. |  |
| Identify any specific arrangements required in the event of the patient requiring resuscitation following a cardiac arrest or other acute medical emergency. |  |
| Identify any actions to be taken in the event of the death of the patient before the end of the treatment period. |  |

| **5.3 - Patient Follow up** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| Identify any specific safety arrangements required in the event of death of the patient before the end of the treatment period. |  |
| Are there specific precautions in the event of the death of the patient at home? |  |

| **5.4 - Staff Safety and Surveillance** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| Specify any health surveillance requirements for staff involved in the work. Has a standard protocol been arranged with Occupational Health to this effect? |  |
| Specify the protective clothing and any other personal protective equipment (PPE) to be used at each stage.  If this is different to the normal PPE provided, please specify where the PPE will be stored and the named individual responsible for its issue. |  |
| Are there any hazards associated with the accidental inoculation of a Health Care Worker with the ATIMP? Specify precautions to be followed. |  |

| **5.5 - Waste Management** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| In addition to standard infection, protection and control precautions, are there any additional safety requirements for handling the patient’s body fluids? |  |
| In addition to standard hospital procedures are any additional safety arrangements required for the disposal of clinical waste from the patient’s room? |  |
| Other than standard arrangements, are any additional safety measures or procedures required for cleaning the patient’s bed linen or laundry? |  |
| Other than standard hospital cleaning procedures, specify any additional arrangements required when cleaning the patient’s room during and at the end of the treatment period. |  |
| Specify the disinfectants to be used at each stage, and the concentrations at which they will be used. |  |
| Specify the arrangements for safe disposal of contaminated materials appropriate for each stage of the work. Specify the arrangements for safe disposal of contaminated materials appropriate for each stage of the work. |  |
| Identify any procedures which will involve sharps, and specify arrangements for their safe use and disposal |  |
| If any waste is to be autoclaved, specify:   * Types of waste * Storage location prior to inactivation, Autoclave cycle parameters * Monitoring & recording of inactivation * Validation of inactivation (e.g. validation of autoclave) * Final disposal route of the wastes. |  |

**5.6 - Emergency procedures**

Details of BLS/ALS training and availability of suitably trained staff for medical cover.

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**5.7 - Information, Instruction, Supervision and Training**

List all relevant SOPs and Codes of Practice specific to this study.

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| --- |
| *e.g. Disposal SOP, Administration of vaccines SOP.* |

Describe the training of all staff at risk of exposure. Include details of record keeping.

|  |
| --- |
| *e.g. GCP and study protocol training.* |

**Section 6: Accommodation**

Where will the ATIMP be stored, handled and administered?

|  |  |  |
| --- | --- | --- |
| **Room** | **Site** | **Responsible Person** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Section 7: Personnel**

**7.1 – Names of key persons directly involved in the research study at site**

|  |  |  |
| --- | --- | --- |
| **Surname** | **Position** | **Employer** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**7.2 – Other personnel at risk from this research study at site**

List other research staff, cleaners, maintenance workers and ancillary staff that may be at risk, but not directly involved in this research study.

|  |  |  |
| --- | --- | --- |
| **Details (including names, if known)** | **Employer** | **Involvement with this clinical research clinical research study and exposure opportunity** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**7.3 – Responsible Persons**

The PI and sub-Investigator will be responsible for managing risks to non-NHS/non-University of Dundee personnel involved in this research study (as per section 1.2 and 1.3).

Who will be providing Occupational Health support for each category of personnel involved in this ATIMP research study?

| **Category** | **Occupational Health Contact** |
| --- | --- |
| NHS Personnel |  |
| Other Personnel |  |

**Section 8: Pharmacy**

**8.1 – Manufacture**

|  |  |
| --- | --- |
| Product, Manufacturer and License status |  |
| Is substitution with a safer product practical? Please provide reasons for your answer. |  |
| Indication |  |
| Presentation |  |
| QP release by |  |
| Is the ATIMP linked to a specific patient?  How is this achieved? |  |
| Is there potential for >1 patient to be treated at the same time? |  |

**8.2 – Shipment**

|  |  |
| --- | --- |
| What container is used for shipment? Is dry ice used? |  |
| What are the temperature requirements? |  |
| Specify arrangements for receipt of the ATIMP |  |

**8.3 – Storage on Site**

|  |  |
| --- | --- |
| Specify arrangements for safe storage of the ATIMP. |  |
| How long is storage allowed/required? |  |
| Has a suitable location been identified? |  |
| If the ATIMP is to be stored in Liquid Nitrogen, specify precautions to prevent the release of the ATIMP during loading or retrieving the product from storage? |  |
| In the event of a breakdown of the storage equipment, detail contingency plans for the transfer to (including the location of) alternative storage |  |
| What security measures are in place? Would you be able to easily and rapidly identify that a sample was missing? Is the storage alarmed? |  |

**8.4 – Preparation/Manipulation**

|  |  |
| --- | --- |
| Specify arrangements for the safe preparation of the ATIMP for administration. |  |
| What are the handling requirements? |  |
| Are suitably trained staff available? |  |
| Have suitable facilities/location been identified? (provide specific location details) |  |
| What is the shelf-life following preparation/manipulation? |  |
| Will laboratory preparation of the ATIMP be required? What facilities will this require (hoods, incubators, centrifuges etc)? |  |
| Will precautions need to be taken against the formation and dissemination of aerosols?  If so, what techniques or equipment could give rise to aerosols and how will these be controlled?  Will a microbiological safety cabinet be required? Dedicated lab? Negative pressure? Sealed centrifuge buckets etc? |  |
| How will spillages or contaminated equipment be dealt with? |  |
| What are the risks associated with spillage? |  |
| How will the above identified risks be mitigated? |  |
| Specify arrangements for the safe transport of the ATIMP to the site of administration.  (If the starting product is received and manipulation processes occur at a different site to patient administration, please detail processes of transport to administration site). |  |

**8.5 – Prescription**

|  |  |
| --- | --- |
| How will the ATIMP be prescribed? |  |

**8.6 – Disposal**

|  |  |
| --- | --- |
| What are the arrangements for disposal? |  |

**8.7 – Other Issues**

|  |  |
| --- | --- |
| Are there any other risk considerations to Staff and Public? |  |
| If so, how will the above identified risks be mitigated? |  |
| What is the reporting process for an Adverse Drug Reaction? |  |
| Is Advanced Therapy Investigational ATIMP? Batch Number recorded at each patient visit? |  |
| Are patient information risk mitigation details (e.g. Alert Card/ Patient Information Leaflet) available? |  |

|  |  |
| --- | --- |
| PI Name | Title |
| Signature | Date |

**Submission details**

Please send your competed Risk Assessment form, along with the required documents outlined below, to the Secretary of the ATGM Safety Committee at [TASCQA@dundee.ac.uk](mailto:TASCQA@dundee.ac.uk)

• Protocol

• Investigator Brochure/details

• IRAS Project Information Sheet

• Relevant publications related to the ATMP (if applicable)

• MSDS Safety Sheet

• Documents submitted to GTAC with favourable opinion letter (for gene therapy only)

• PI’s CV

**Abbreviations**

ATGMSC Gene Modification Safety Committee

ATIMP Advanced Therapy Investigational Medicinal Product

BLS/ALS Basic Life Support/Advanced Life Support

GMO/GMM Genetically Modified Organism/Genetically Modified Microorgansim

GTAC Gene Therapy Advisory Committee

HSE Health & Safety Executive (HSE)

IRAS Integrated Research Application System

MHRA Medicines & Healthcare products Regulatory Agency

PI Principal Investigator

PPE Personal Protective Equipment

QP Qualified Person

REC Research Ethics Committee

SOP Standard Operating Procedure

TASC Tayside Medical Science Centre